REMARKS

Claims 1, 6-7, 20, 23 and 28 have been amended to correct a spelling error.

Claims 29-38 have been canceled as directed to non-elected without prejudice for prosecution in a subsequent application to be filed

Claims 1-28 and new claims 39-47 remain before the Examiner. Support for new claims 39-47 is provided by the specification and claims as originally filed. New claims 39-47 are directed to the subject matter of Group I. No new matter has been introduced and entry of the amendment is respectfully requested.

Attached hereto is a marked-up version of the changes made to the claims by the instant amendment. The attached page is captioned "**Version with markings to show changes made.**"

Applicant has carefully reviewed the Restriction Requirement mailed October 2, 2001 and request reconsideration in light of the above amendments and following discussion.

The Examiner has restricted claims 1-28 into Groups I and II by alleging that they "differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success." Applicants respectfully assert that Groups I and II do not represent patentably distinct inventions. As an initial matter, Applicants point out that at least the alleged differences in "objectives" and "criteria of success" do not appear to be proper bases for restriction since restriction requires distinctness and independence between the claimed inventions AND a serious burden of search.

In the instant case, the invention of claims 1 and 20 are directed to methods comprising specific acts which determine the scope and subject matter of the claims and thus the scopes of the search necessary to examine the claims. The claims of Group I include the act of determining 20P1F12/TMPRSS2 expression in biological samples which is associated with

dysregular cellular growth (i.e., neoplasms) in the individual from whom the sample is taken. The claims of Group II also include the act of determining 20P1F12/TMPRSS2 expression in biological samples and the correlation with dysregular cellular growth which are indicative of cancer. By view of the claims, 20P1F12/TMPRSS2 expression and dysregulated cellular growth are inherently compared in the invention of Group II. Given the inclusion of the same acts (literally or inherently) in the inventions of both Groups, it is not understood how the method claims in Groups I and II could then be patentably distinct from one another. Therefore, it is believed appropriate to examine the claims included in Groups I and II in a single application.

Moreover, the subject matter of Group II is related to the subject matter of Group I as combination (comprising determining 20P1F12/TMPRSS2 expression in biological samples and the correlation with dysregular cellular growth) to the subcombination of determining 20P1F12/TMPRSS2 expression in biological samples (Group I). The standards for Restrictions and combination/subcombinations are set forth at MPEP 806.05 through 806.05(d). Because no support to meet the standards set forth therein have been presented, Applicants respectfully submit that no basis for the restriction between Groups I and II exists.

For all of the above reasons, Applicants believe the Restriction between these Groups is inappropriate and may thus be properly withdrawn.

In the event that the Restriction Requirement is maintained, Applicants hereby elect with traverse Group I, claims 1-19 and new claims 39-47. Additionally, Applicants elect the following species as set forth by the Restriction Requirement: mRNA expression (with respect to claims 2 and 14), immunoassay (with respect to claims 4 and 16), blood and serum (with respect to claims 5 and 13), and prostate cancer (with respect to claims 6 and 11). This election

is made with the understanding that the requirement for election of species is to assist the Examiner with the start of the search process and that should the elected species be found to be free of the prior art, the remaining species will all be searched and examined.

Applicant requests examination of the elected subject matter on the merits.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 511582000820.

Respectfully submitted,

Dated: November 2, 2001 By: _____

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Version with markings to show changes made.

Kindly amend the claims as follows:

Please cancel claims 29-38.

Please amend the claims as follows:

1. (Amended) A method of examining a biological sample for evidence of dysregulated [disregulated] cellular growth comprising comparing the status of 20P1F12/TMPRSS2 in the biological sample to the status of 20P1F12/TMPRSS2 in a corresponding normal sample, wherein alterations in the status of 20P1F12/TMPRSS2 in the biological sample are associated with dysregulated [disregulated] cellular growth.

6. (Amended) The method according to claim 1, wherein the dysregulated [disregulated] cellular growth is indicative of a prostate cancer.

7. (Amended) The method according to claim 1, wherein the dysregulated [disregulated] cellular growth is indicative of a colon cancer.

20. (Amended) A method of detecting a cancer in an individual comprising

(a) examining 20P1F12/TMPRSS2 gene expression in a test biological sample obtained from the individual; and

(b) examining the individual for the presence of a factor associated with dysregulated [disregulated] cellular growth;

wherein a coincidence of 20P1F12/TMPRSS2 gene expression in the test biological sample obtained from the individual and the presence of the factor associated with dysregulated [disregulated] cellular growth is indicative of the cancer.

23. (Amended) The method according to claim 20, wherein the factor associated with dysregulated [disregulated] cellular growth is an increase in the level of prostate specific antigen expression.

28. (Amended) The method of claim 27, wherein the 20P1F12/TMPRSS2 evaluated in the test biological sample is secreted from cells exhibiting dysregulated [disregulated] growth.